K120568

MAR 2 9 2012

510(k) Summary

According to the requirements of 21 CFR §807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Company:	Abbott Laboratories
Division:	Abbott Diabetes Care, Inc.
Street Address:	1360 South Loop Road
City, State Zip:	Alameda, CA 94502
Telephone No:	510-749-5400
Fax No:	510-864-4791
Contact Person:	Arul Sterlin; Tel No. 510-864-4310; Fax No. 510-864-4791; arul.sterlin@abbott.com
Proprietary Name:	FreeStyle InsuLinx Blood Glucose Monitoring System
Common Name:	Glucose Test System
Classification Name:	System, test, blood glucose, over the counter, Glucose, Class II (21 CFR§ 862.1345) Product codes: NBW; Glucose Dehydrogenase, Glucose, Class II (21 CFR§ 862.1345) Product codes: LFR;
Predicate Device:	FreeStyle InsuLinx Blood Glucose Monitoring System (k111874)
Legal Manufacturer:	Establishment: Abbott Diabetes Care Inc. 1360 South Loop Rd. Alameda, CA 94502 Registration Number: 2954323

Indications For Use:

The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The FreeStyle InsuLinx Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The FreeStyle InsuLinx Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use.

The FreeStyle InsuLinx Blood Glucose Test Strips are for use with the FreeStyle InsuLinx Blood Glucose Meter to quantitatively measure glucose in capillary whole blood samples drawn from the fingertip.

Description of the Device:

The FreeStyle InsuLinx Meter, in conjunction with the FreeStyle InsuLinx Test Strips works on the principal of coulometric biosensor technology, measuring glucose by its reaction with Glucose Dehydrogenase (GDH) in blood samples or control solutions, through electrochemical mediation.

The device automatically logs blood glucose results and other events to create a customized logbook. The FreeStyle InsuLinx System has a large touch screen and a user interface designed for an easy user experience.

Patient and Healthcare Professionals can pre-program audible and visual reminders for blood glucose testing, or other individual needs.

Weekly messages feature assist the patient in identifying patterns in their blood glucose results. Using a rolling report, the measured glucose values are summarized according to the proportion within, above, or below the predetermined target range entered by the patient or HCP. These

results are displayed in a simple graphical format and include a count of the tests performed. An additional algorithm compares the prevailing blood glucose levels during the preceding week with simple messages relating to achievement versus target glucose levels.

The FreeStyle InsuLinx System has 'plug and play' software that automatically installs on a computer without the need for a CD or internet access (via the meter's USB port and a provided cable). It also provides access to the structured reports for both the healthcare professionals and patients.

The FreeStyle Auto-Assist software produces six different reports to facilitate discussion between patients and their health care professionals in the review, analysis, and evaluation of historical blood glucose test results to support an effective diabetes management program. The software also shows trends in blood glucose data in both graphical and text format for guided interpretation.

- The **Snapshot Report** is a general summary of the data for a specified date range.
- The **Modal Day Report** shows the daily patterns of blood glucose levels over a specified date range
- The **Logbook Report** is a table of blood glucose for each day in the specified date range.
- The **Daily Statistics Report** provides an overview of blood glucose over the date range in a series of charts and tables.
- The **Meal Event Averages Report** compares the before and after meal blood glucose level averages for the morning, mid-day and evening times over the specified date range.
- The **Meter Settings Report** shows current meter settings.

These reports provide detailed information on glucose monitoring, and are designed to enable healthcare professionals and patients to assess the effectiveness of diabetes management and then plan appropriate changes to therapy regimens.

Principles of Operation:

The FreeStyle InsuLinx Meter (in conjunction with FreeStyle InsuLinx blood glucose test strips) utilizes coulometric biosensor technology to quantitatively measure the glucose concentration in whole blood samples and in FreeStyle Control Solutions.

The FreeStyle InsuLinx Meter measures glucose electrochemically. The glucose biosensor is capable of recognizing the glucose present in whole blood or control solutions by virtue of the glucose specificity of the enzyme glucose dehydrogenase (GDH) present on the glucose test strip. The electrons liberated by this reaction are transferred via a co-factor and mediator to the meter where they are read as a small electrical current. The current is integrated over the analysis time to generate charge which is directly proportional to the level of the glucose in the applied sample.

The FreeStyle InsuLinx Meter does not require calibration prior to use with the FreeStyle InsuLinx Test Strips. The device is prepared for use by inserting a FreeStyle InsuLinx test strip in the test strip port. Upon strip insertion, the meter will turn on automatically and perform a display check. The 'apply blood' message is displayed for the user to apply blood to the test strip until the meter begins the test. Blood detect will occur when the meter detects trigger current from the test strip, when enough blood has covered the strip electrodes. Following the blood detect, the meter performs the glucose assay measurement.

Description of Modification:

The basis for this submission, is to include the FreeStyle Lancing Device and Lancets in the FreeStyle InsuLinx System Kit, which is packaged with the following components and accessories listed below.

(A) FreeStyle InsuLinx Meter

(B) 10 count vial of FreeStyle InsuLinx Test Strips (may be sold separately)

(C) FreeStyle Auto-Assist software (resides in the FreeStyle InsuLinx Meter)

(D) Carrying Case

(E) Owner's Booklet

(F) Quick Start Guide

(G) USB Cable

(H) FreeStyle Control Solutions (may be obtained by contacting Customer Service)

Comparison to Predicate Device:

The similarities between the modified FreeStyle InsuLinx System and the predicate are highlighted below:

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (k111874)	Modified FreeStyle InsuLinx Blood Glucose Monitoring System
CHARACTERISTICS		
Indications for Use	The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The FreeStyle InsuLinx Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The FreeStyle InsuLinx Blood Glucose Monitoring System	Same

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (k111874)	Modified FreeStyle InsuLinx Blood Glucose Monitoring System
	should not be used for the diagnosis of or screening for diabetes or for neonatal use. The FreeStyle InsuLinx Blood Glucose Test Strips are for use with the FreeStyle InsuLinx Blood Glucose Meter to quantitatively measure glucose in capillary whole blood samples drawn from the fingertip.	
Classification Product Code	NBW, LFR	Same
Fundamental Technology	The FreeStyle InsuLinx Meter (in conjunction with blood glucose test strips) utilizes coulometric biosensor technology to quantitatively measure the glucose concentration in whole blood samples and in FreeStyle Control Solutions	Same
Enzyme	GDH – FAD	Same
Sample Type	Whole blood & capillary	Same
Test Sites	Finger	Same
Sample Volume	0.3 µL	Same
Measurement Glucose Range	20 to 500 mg/dL	Same
Meter Operating Humidity	5 to 90% Relative Humidity, Non-Condensing	Same
Storage Operating Temperature	-4°F to 140°F (-20°C to +60°C)	Same
Precision	At glucose levels below 75mg/dL average SD is ≤ 5mg/dL and at glucose levels ≥ 75mg/dL average CV is ≤ 5%	Same
Accuracy	95% of results should fall within ± 15mg/dL of the comparative method results at glucose concentrations <	Same

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (k111874)	Modified FreeStyle InsuLinx Blood Glucose Monitoring System
	75mg/dL and within ±20% at glucose concentrations ≥ 75 mg/dL	
Measurement Module	FreeStyle Super Speedy Algorithm (5 seconds)	Same
Double Application	60 seconds	Same
Meter Operating Temperature	40°F to 104°F (4°C to 40°C)	Same
Meter Operating Pressure	Up to 10000 feet (3048 meters)	Same
Hematocrit	15% - 65%	Same
Data Management	FreeStyle Auto-Assist software	Same
Application Software	Software running on the meter provides the User with an Electronic Logbook, Data Management and Diabetes Management Tools	Same
Measurement Time	average 5 seconds	Same
Coding	No coding required	Same
Microprocessor	ST	Same
User Preferences	The device lets the user set: • Time and Date Changes • Time and Date Formats • Audible Alert • Personalized test screen • Weekly Message glucose ranges • Personalized notes and reminders	Same
Summary Statistic Elements	• Snapshot Report • Modal Day Report • Logbook Report • Daily Statistics Report • Meal Event Averages Report • Meter Settings Report • Weekly messages	Same
Communications	"Plug and Play" device set-up	Same

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (k111874)	Modified FreeStyle InsuLinx Blood Glucose Monitoring System
	screen that enables configuration of the device through the PC	

The differences between the modified FreeStyle InsuLinx System and the predicate are highlighted below:

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (k111874)	Modified FreeStyle InsuLinx Blood Glucose Monitoring System
CHARACTERISTICS		
Accessories	**(A)** FreeStyle InsuLinx Meter **(B)** 10 count vial of FreeStyle InsuLinx Test Strips (may be sold separately) **(C)** FreeStyle Auto-Assist software (resides in the FreeStyle InsuLinx Meter) **(D)** Carrying Case **(E)** Owner's Booklet **(F)** Quick Start Guide **(G)** USB Cable **(H)** FreeStyle Control Solutions (may be obtained by contacting Customer Service)	**(A)** Same **(B)** Same **(C)** Same **(D)** Same **(E)** Same **(F)** Same **(G)** Same **(H)** Same **(I)** FreeStyle Lancing Device **(J)** FreeStyle Lancets

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Abbott Diabetes Care Inc.
c/o Arul Sterlin
1360 South Loop Rd.
Alameda, California 94502

MAR 2 9 2012

Re: k120568
Trade Name: FreeStyle InsuLinx Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, LFR
Dated: February 24, 2012
Received: February 29, 2012

Dear Mr. Sterlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120568

Device Name: FreeStyle InsuLinx Blood Glucose Monitoring System

Indications For Use:

The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The FreeStyle InsuLinx Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

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The FreeStyle InsuLinx Blood Glucose Test Strips are for use with the FreeStyle InsuLinx Blood Glucose Meter to quantitatively measure glucose in capillary whole blood samples drawn from the fingertip.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K120568